REMARKS

In the Office Action, Claims 1, 6-7, and 22-27 were objected to under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has possession of the claimed invention. Claims 1 and 6-11, and 22-27 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention. Claims 8-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 1, 6, 22, 25 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Falconer et al., as evidenced by the teachings of Kartinos *et al.* and Mullins. Claims 1, 6, 22, 25 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of Kartinos *et al.* and Mullins. Claims 1, 6, and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Love et al.

Claims 1, 6, and 22-27 are now pending in the application. Claims 1, 6-11 and 22-27 have been rejected. Claims 2-5 and 7 were previously cancelled. Claims 12-21 and 28-33 were previously withdrawn due to restriction of invention and are now been canceled. Claims 8-11 have also been cancelled. Reexamination and reconsideration of the claims are respectfully requested.

Claim Objections

Claims 8-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 1 recites a method for increasing retrievable fluid from a breast duct. Claims 8-11 positively recite the additional step or steps of collecting or analyzing ductal fluid. Thus, by definition, Claims 8-11 limit the scope of Claim 1 by requiring the additional steps of retrieving the ductal fluid sample obtained through the method described in Claim 1. Although Applicant believes that Claims 8-11 satisfy the requirement of 37 CFR 1.75(c), in order to expedite prosecution, Applicant has cancelled Claims 8-11. Applicant respectfully requests reconsideration and withdrawal of the present objection.

Rejection of Claims 1 and 6-11 Under 35 U.S.C. §112, First Paragraph Should be Withdrawn

Claims 1, 6, 7, and 22-27 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention. Claim 7 was previously cancelled and claims 8-11 have subsequently been canceled rendering the rejections moot.

Claims 1 and 6-11 and 22-27 were rejected because, as the examiner states, the specification "...does not reasonably provide enablement for the claim-designated method comprising the intraductal administration of any and all amounts of any and all agents recited in the Markush group of Claim1." This rejection is respectfully traversed for the reasons described below.

The Examiner's rejection under 35 U.S.C. §112, first paragraph is based upon the notion that one of ordinary skill in the art would be unable to make and use the entire scope of the claimed invention without undue experimentation. To support such a *prima facie* case, the Examiner states that "[w]hile it may be possible that particular agents recited in the Markush group of Claim 1 could increase the secretion of the ductal fluid into a breast duct of a patient such as hormones, it is highly unlikely that any and all of the claim-designated agents could increase secretion of ductal fluid into a breast duct." (see page 4 second paragraph of 3/30/2005 Office Action). To answer the Examiner's rejection, it must be remembered that a claim can encompass "inoperative" embodiments so long as one of ordinary skill can ascertain this without undue experimentation. The Examiner has explicitly stated that the specification is enabled for a method of preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to a patient an effective amount of mannitol that increases the ductal fluid collection from a breast duct of a patient (see page 2 of the 3/30/2005 Office Action). As such, one of skill in the art would conclude that the administration of high molecular weight hygroscopic agents into a breast duct would potentially increase the amount of ductal fluid within the breast duct. Such an assessment is routinely performed in the art. Hence, inoperative embodiments encompassed by claim 1 (i.e., agents that are non-hygroscopic) could be easily identified by one of skill in the art without undue experimentation. Accordingly, claims 1, 6 and 22-27 are enabled and the rejection should be withdrawn.

The Applicant also disagrees that there is no enablement for any and all amounts of any and all agents recited in the Markush group of Claim1. Since mannitol is one member of the

Markush group of Claim 1, it is simply a misstatement by the Examiner that there is no enablement in the specification for any amount of any agents. Also, the Examiner has not provided any reasoning as to why dependent claims such as Claims 23, 24, and 25, do not satisfy the criterion of 35 U.S.C. §112, first paragraph. In fact, since the Examiner has explicitly stated that mannitol is enabled, it is the Applicant's position that, without acceding to the merits of these rejections, the Examiner should have allowed Claim 23 (which contains mannitol and another high molecular weight sugar sorbitol) if written as an independent claim. Likewise, Claims 24 and 25 should have been searched and, absent the discovery of relevant prior art, allowed.

Claims 1, 6, 7, and 22-27 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.

Claims 1 and 6-11 and 22-27 were rejected because, as the examiner states, "....the specification as originally filed does not particularly point out or specifically distinguish agents that increase the secretion of fluid into a breast duct when the agent is intraductally administered thereto the breast duct of a patient." This rejection is respectfully traversed for the reasons described below.

Applicant submits that there is sufficient written description for "an agent that increases the secretion of ductal fluid into a breast duct" to enable one skilled in the art to which it pertains to make and/or use the invention, as required by section 112, first paragraph (see M.P.E.P. 2163.02).

"Written description may be satisfied through disclosure of relevant identifying characteristics, *i.e.*, structure, other physical and/or chemical characteristics, functional

characteristics when coupled with a known or disclosed correlation function and structure, or some combination of such characteristics." *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, First Paragraph, Written Description Requirement.* Moreover, "[a] specification may, within the meaning of 35 U.S.C. § 112, first paragraph, contain a written description of a broadly written claimed invention without describing all species that claim encompasses." *Utter v. Jiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988).

Thus, the Applicant submits that the terms "nonabsorbable biocompatible solution", "a protein", "a colloid", a polymer", "a synthetic colloid", "an antibody", "an organic molecule", "a ductal orifice dilator", or a "a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration" are clear and definite based on the plain meaning of the terms. The Examiner then proceeds to state that "...these agents constitute anything". This is demonstrably untrue. All of the terms have a clear and specific meaning. For example, although the term "protein" may contain numerous examples, it is not true that such a term encompasses "anything" as stated by the Examiner. Proteins are a high molecular weight organic compounds that consist of amino acids joined by peptide bonds. Likewise, an antibody is a high molecular weight glycoprotein comprised of variable binding domains (Fab) and constant binding domains (Fc). One skilled in the art would be very familiar with all of the terms cited by the Examiner.

Also, as mentioned previously, there are apparently numerous examples of agents within the Markush group of Claim 1 that satisfy the written description requirement of 35 U.S.C. §112, first paragraph (e.g., mannitol, sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose,

polyethyleneglycol (PEG), maltodextrin, dextran, dextran 70, hydroxyethyl starch, fluid gelatin, albumin, a hormone, silymarin, oxytocin, or prolactin). As such, the Examiner has not provided any reasoning as to why dependent claims such as Claims 23, 24, and 25, do not satisfy the written description requirement. In fact, since the Examiner has explicitly stated that mannitol supported by the specification, it is the Applicant's position that, without acceding to the merits of these rejections, the Examiner should have allowed Claim 23 (which contains mannitol and another high molecular weight sugar sorbitol) if written as an independent claim. Likewise, Claims 24 and 25 should have been searched and, absent the discovery of relevant prior art, allowed.

Thus, for the reasons stated above, the Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Rejection of Claims 1, 6, 22, 25 and 27 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1, 6, 22, 25 and 27 were rejected to under 35 U.S.C. § 102(b) as being anticipated by Falconer *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins. Claim 1 was rejected because, as the examiner states "...Falconer *et al* teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins)." Applicant respectfully traverses.

Claim 1 recites a method preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is selected from the group consisting of ... a nonabsorbable biocompatible solution. The examiner argues that Falconer *et al* anticipates Claim 1 because it shows that increasing the amounts of prolactin increases the water content of wet tissue in treated mammary gland tissue. Applicant disagrees. Falconer *et al.* describes an in vivo experiment in rabbits to measure the effect of prolactin and ouabain on mammary alveolar tissue. Falconer *et al.* does <u>not</u> teach a method for administering intraductally to a patient an agent that increases retrievable ductal fluid <u>from a breast duct</u>. As evidenced on page 185, Column 1, lines 4-8, Falconer *et al.* explicitly states that "From these results we conclude that *in vitro* and *in vivo* prolactin has significant influence upon Na+ and K+ content (and therefore Na+/K+ ratio) of mammary alveolar <u>tissue</u>". Alveolar tissue is comprised of glandular tissue and secreting cells that surround the ductal system (see page 182, Column 2, lines 29-33). Therefore, Falconer *et al.* does not disclose that prolactin and ouabain increases water content in breast ducts, but instead, discloses an increase in water content of the surrounding alveolar tissue. There is no teaching or suggestion in Falconer *et al.* of an agent that increases retrievable ductal fluid from a breast duct.

The Examiner then goes on to state that "...the method taught by Falconer *et al.* is a one step process comprising the intraductal administration of the same ingredient as disclosed by Applicant. Thus, a method for increasing retrieval fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible

solution, is inherent to the method of treatment taught by Falconer." Applicant respectfully traverses.

As mentioned previously, Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Dextran Blue 2000) as an agent to increase retrievable ductal fluid from a breast duct. There is nothing Falconer *et al.* to suggest that Dextran Blue 2000 can increase the amount of fluid in a breast duct. In fact, as evidenced on page 182, Column 2, lines 13-15, Falconer *et al.* explicitly states that Dextran Blue 2000 is used to "...locate the injected glands at the time of removal". Therefore, the method of the present invention cannot be inherent to the method of Falconer *et al.*, because there is nothing in Falconer *et al.* that suggests any agent that increases retrievable ductal fluid from a breast duct.

Likewise, the Examiner has not provided any reasoning as to why dependent claim 25 is anticipated by Falconer *et al.* There is simply no teaching or suggestion at all in Falconer *et al.* of the use of polyethyleneglycol (PEG), maltodextrin, dextran, or dextran 70 to increase the amount of fluid in a breast duct.

Because Falconer *et al.* does not anticipate neither Claim 1 nor dependent Claims 6, 22, 25 and 27, the rejection should be withdrawn.

Claims 1, 6, 22, 25 and 27 were rejected to under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins. Claim 1 was rejected because, as the examiner states "Martyn teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH

and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins)." Applicant respectfully traverses.

As mentioned previously, Claim 1 recites a method preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Martyn *et al.* describes an *in vivo* experiment in rabbits to measure the effect of prolactin and progesterone on lipogenic-enzyme activity and glycerolipid synthesis. Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Blue Dextran 2,000,000) as an agent to increase retrievable ductal fluid from a breast duct. In fact, as evidenced on page 326, Column 1, lines 28-41, as well as Table 4 on page 326, Blue Dextran mixed with Phosphate-buffered saline had no effect on fatty acid synthesis. Therefore, the method of the present invention cannot be inherent to the method of Martyn *et al.* because there is nothing in Martyn *et al.* that suggests any agent that increases retrievable ductal fluid from a breast duct.

Therefore, because Martyn *et al.* does not anticipate Claim 1 nor dependent Claims 6, 22, 25 and 27, the rejection should be withdrawn.

The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1, 6, and 22 are rejected under 35 U.S.C. 102(b) as being unpatentable over U.S. Patent No. 6,221,622 to Love. Applicants traverse this rejection.

Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. The Examiner states that "[g]iven the claims the broadest interpretation of the term 'an organic molecule', the Examiner regards the physiological saline washing fluid taught by Love as an 'organic molecule'." The Applicant strongly disagrees.

A saline solution is a sterilized concentration (0.15 molar) of sodium chloride in water. Sodium chloride is an inorganic salt. It is not reasonable for the Examiner to take the position, without providing any evidence to support such an assumption, that a saline solution is an organic molecule. Since it is clear that a saline solution is not an organic molecule, the remainder of the Examiner's arguments concerning the Claims 1, 6, and 22 being anticipated by Love cannot stand. There is nothing in Love that either teaches or suggests the use of an organic molecule for increasing the retrievable ductal fluid from a breast duct.

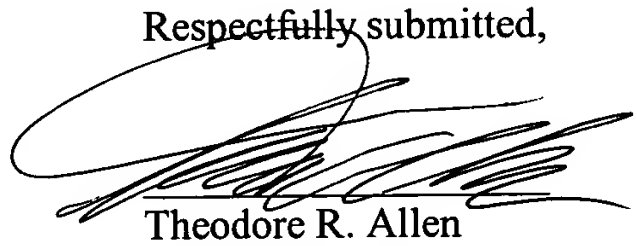
Therefore, because Love does not anticipate neither Claim 1 nor dependent Claims 6 or 22, the rejection should be withdrawn.

CONCLUSION

In light of the amendments and arguments presented above, Applicant respectfully submits that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.023011.

Respectfully submitted,



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